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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
BSX 219/10026334

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed name _____

Application Number	Filed
09/963,676	09/27/2001

First Named Inventor: Yem Chin

Art Unit	Examiner
3731	EREZO, DARWIN P

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☐ attorney or agent of record.
Registration number _____

☒ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 30,845

Signature

THOMAS S. HAHN
Typed or printed name

202-662-0278
Telephone number

July 6, 2006
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Yem Chin et al.

Confirmation No.: 8991

Application No.: 09/963,676

Art Unit: 3731

Filed: September 27, 2001

Examiner: Darwin P. Erezo

For: METHOD AND APPARATUS FOR MEASURING AND CONTROLLING BLADE DEPTH OF A TISSUE CUTTING APPARATUS IN AN ENDOSCOPIC CATHETER

PRE-APPEAL BRIEF REQUEST FOR REVIEW

MS AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Concurrently filed are a Notice of Appeal with fee and an executed Pre-Appeal Brief Request for Review (PTO/SB/33).

All pending claims currently stand rejected under 35USC§103 as being unpatentable over US Patent No. 5,425,376 (Banys et al.) in view of US Patent No. 6,574,497 (Pacetti), and in further review of US Patent No. 4,588,399 (Nebergall et al.). These rejections are reported in a final action dated February 6, 2006, and they are further continued in an advisory action dated April 17, 2006. It is submitted that clear factual and legal deficiencies in the record preclude establishment of *prima facie* rejections in all instances for these pending claims.

"To establish a *prima facie* case of obviousness... the prior art reference (or references when combined) must teach or suggest all the claim limitations" (MPEP§2143). It is submitted

that certain recited claim limitations discussed below are not taught or suggested in the asserted references.

Rejected claims 27, 31 and 35 are independent, all other reported rejected claims are dependent from one or the other of these three independent claims.[1]

Independent claims 27 and 31 are method claims and both recite among other limitations "determining length of exposure of a tissue cutting device from a distal portion of a lumen of an endoscope catheter." In identical substantive content, independent apparatus claim 35 recites the structural limitation that the length a tissue "cutting member is extended from said opening [in a lumen] is a length said radiopaque indicia is moved in said lumen". It is submitted that no asserted reference or proper combination of asserted references disclose or suggest extension of a device for cutting tissue beyond a distal end of a lumen. The specific above identified limitations recited in each of the independent claims and the explicit and inherent disclosure failures in the asserted references vis-à-vis these limitations are clear on their faces so as to present a fatal deficiency in the asserted rejections, which, therefore, fail to be *prima facie* rejections. These deficiencies are submitted as being fatal and ripe for prompt decision under the now instituted pre-appeal brief conference pilot program. (1296 Off. Gaz. Pat. Office 67 (12 July 2006); and, as extended 1303 Off. Gaz. Pat. Office 21 (7 February 2006)).

The primary reference, Banys et al., is asserted in the advisory action as teaching "the method of moving a radiopaque needle within the catheter to locate the needle next to a tissue would inherently teach the method of using a radiopaque material for determining displacement

[1] If each of the three independent claims recites at least one limitation not taught or suggested in the asserted references then all of their dependent claims are nonobvious. "Dependent claims are nonobvious under 103 if the independent claims from which they depend are nonobvious." (Citations omitted). *In re Fine*, 5USPQ2d1596, 1600 (Fed.Cir.1988).

of a cutting device (needle) from a catheter lumen." (Paragraph 11). It here is submitted, without conceding any issue or argument concerning what Banys et al. do or do not disclosure or suggest for use of "radiopaque material" or "determining displacement" of structures, that Banys et al. absolutely, by explicit teaching, fail to disclose or suggest extending a device capable of cutting tissue beyond a distal end of a lumen.

Banys et al. disclose an apparatus described as including a cannula tube 44 and a needle 16 inserted in the cannula tube 44 for obtaining biopsy samples, (e.g. see col. 5, lines 40-42). In and of itself the Banys et al. needle 16 is not a "cutting device" as asserted in the advisory action. What Banys et al., disclose are separate mechanisms that must be structurally combined at the distal end of cannula tube 44 for cutting tissue. These mechanisms include a "[l]ateral opening 28... formed in the wall of needle 16... with at least one sharp cutting edge 27 near the distal end of opening 28, to assist in the cutting of a sample from the selected tissue." (col. 5, lines 4-8). Thus, the Banys et al. needle 16 by specific disclosure does not include all structures for a tissue cutting device, but only a portion "to assist in the cutting of a sample". The additional required Banys et al. structure for tissue cutting includes the "[d]istal end 56 of cannula tube 44 [that] has a sharp cutting edge to assist in cutting a sample from the selected tissue". (col. 5, lines 12-14). Most specifically Banys et al. disclose:

> The physician can maneuver the distal end of needle 16, which can be radiopaque for ease of viewing, to place a sample of the tissue within opening 28 of needle 16. Cannula hub 46 is then pushed forward along locking barrel 18, to the position shown in FIG. 4, covering opening 28 and cutting a sample of the tissue off inside needle 16. (Col. 6, lines 8-14, the Banys et al. Figs. 2, 3 and 4 are reproduced below).

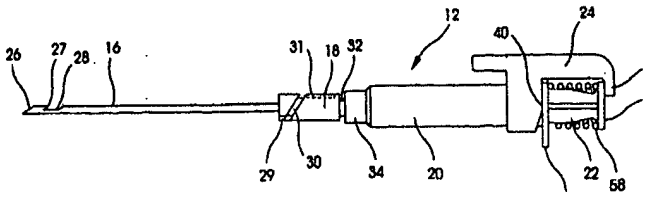

Fig. 2

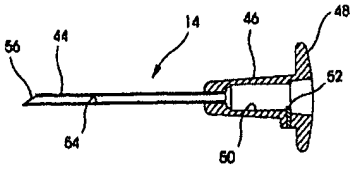

Fig. 3

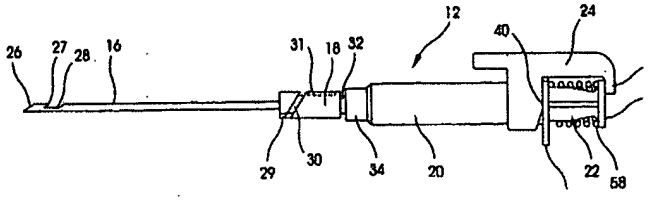

Fig. 4

The totality of the Banys et al. mechanism for cutting tissue is not just needle 16 but requires the needle 16 lateral opening 28 with cutting edge 27 to be brought into cannula tube 44 and thereby past distal end 56 in order to have tissue cut by the combination of cutting edge 27 and cannula distal end 56. Thus, Banys et al. does not disclose or suggest an exclusively needle 16 mounted mechanism or device for cutting tissue, but instead explicitly disclosure a combination mechanism to cut tissue at the distal end 56 of cannula tube 44. Banys et al. by these explicit disclosures teach away from subject matter recited in the pending rejected claims that has a tissue cutting devise extended outside a lumen.

To some how modify Banys et al. to have a tissue cutting device extended beyond the distal end of their cannula would unsatisfactorily modify Banys et al. wherein there is "no suggestion or motivation to make the proposed modifications" of their teachings (MPEP§2143.01(V), and *In re Gordon*, 733F2d900, 221 USPQ1125 (Fed. Cir. 1984)). The Banys et al. teachings that render such modifications unsatisfactory include their disclosure that

their described apparatus and method for obtaining a biopsy sample using a needle having a lateral opening is to have the needle inserted into a cannula having "a sharp edge on its distal end, so that advancing the cannula along the needle can cut off the tissue sample that has been maneuvered into the lateral opening of the needle." (Col. 2, lines 52-56).

Neither of the other cited references have been asserted as disclosing or suggesting tissue cutting devices extended beyond the end of a lumen for tissue cutting nor are they understood to disclose or suggest such structures.

This Pre-Appeal Brief Request For Review is submitted without waiver as to raising the above discussed facts and law or any other facts of record in an appeal to the Board of Patent Appeals and Interferences if such is required.

In view of the above discussions it is submitted and believed that the asserted *prima facie* rejections of claims of record should be withdrawn. As such it is submitted that the pending application is in condition for allowance.

Dated: July 6, 2006

Respectfully submitted,

Thomas S. Hahn
Registration No. 30,845
FULBRIGHT & JAWORSKI LLP
801 Pennsylvania Avenue, NW
Washington, D.C. 20004
(202) 662-0200
(202) 662-4643 (Fax)